

EXHIBIT A

Teresa Irwin, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,) MASTER FILE NO.
PELVIC REPAIR SYSTEM) 2:12-MD-02327
PRODUCTS LIABILITY)
LITIGATION)
MDL 2327

-----)
Daphne Barker)
Case No. 2:12-cv-00899)
JOSEPH R. GOODWIN
Maria Eugenia Quijano) U.S. DISTRICT JUDGE
Case No. 2:12-cv-00799)
Sherry Fox)
Case No. 2:12-cv-00878)

- - -
Friday, March 25, 2016

- - -
GENERAL TVT

Videotaped Deposition of
TERESA IRWIN, M.D. taken pursuant to notice,
was held at the offices of Bowman and Brooke,
LLP, 2901 Via Fortuna Drive, Suite 500,
Austin, Texas, beginning at 8:19 a.m., on the
above date, before Micheal A. Johnson,
Registered Diplomate Reporter, Certified
Realtime Reporter, and Notary Public for the
State of Texas.

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<p style="text-align: right;">Page 34</p> <p>1 of possibility of -- what you're thinking 2 could be a possibility that's not expressed 3 in that report? 4 A. Well, in -- so are you asking 5 me in general to the TVT or -- 6 Q. I'm asking -- go ahead. I'm 7 sorry. I cut you off. 8 A. I guess I want to be a little 9 more specific in terms of what directly 10 you're alluding to, because there could be 11 several -- I can't include every little thing 12 that I -- you know, that's possible that I 13 might have an opinion on, if it hadn't been 14 brought up. Do you understand what I mean? 15 Q. I think I do. And I'm -- 16 let's -- I'm just trying to figure out, to 17 the best of your ability, did you include all 18 the -- let me ask you this. Did you include 19 all the opinions you intend to testify about 20 in the report that's marked as Exhibit 6? 21 A. I intend to testify on the 22 opinions that are presented here. If you ask 23 me a question that may not be in here, I will 24 do my best to answer it.</p>	<p style="text-align: right;">Page 36</p> <p>1 of pelvic mesh? 2 A. I have not. 3 Q. Have you ever done any research 4 concerning the design of pelvic mesh? 5 A. I've -- in terms of the 6 material types and -- any part of the design? 7 Q. Any part of the design. 8 A. Yes, I've done research on it, 9 yes, sir. 10 Q. Okay. What research have you 11 done on the design of pelvic mesh? 12 A. Looking at the literature in 13 terms of the types of mesh types, including 14 the weight and pore size and type of material 15 used. 16 Q. Let's go -- let's -- let me 17 define what I mean by "research." I'm not 18 talking about reading and reviewing 19 literature. 20 A. I understand now. 21 Q. I'm talking about looking at 22 the specifics of the design of pelvic mesh to 23 determine, you know, okay, we need to do this 24 with it, it needs to have this many -- this</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. Okay. And are all the bases 2 for your opinions listed within that report? 3 A. They should be. 4 Q. And I may have asked this, and 5 I apologize, it's -- before today, have you 6 ever served as an expert in any litigation 7 involving pelvic mesh? 8 A. I have not. 9 Q. Do you consider yourself an 10 expert in pelvic mesh design? 11 A. I consider myself an expert in 12 pelvic floor surgery and in the materials 13 that I use to perform those surgeries, as 14 well as knowing the specifications that are 15 ideal for the pelvic floor cavity. 16 Q. Do you have a background or 17 degree in the design of medical devices? 18 A. I do not have a degree in that 19 particular field. 20 Q. Okay. Have you ever designed a 21 pelvic mesh? 22 A. I have not. 23 Q. Have you ever consulted with a 24 pelvic mesh manufacturer regarding the design</p>	<p style="text-align: right;">Page 37</p> <p>1 is how it needs to be knitted, this is what 2 it needs to be made of, this is -- 3 A. Yes, sir, I misunderstood your 4 question. I apologize. I have not. 5 Q. Okay. Have you ever published 6 any peer-reviewed articles regarding the 7 design of pelvic mesh? 8 A. I have not. 9 Q. Okay. Do you consider -- do 10 you consider yourself an expert in the pore 11 size of pelvic mesh? 12 A. I consider myself an expert in 13 knowing what's ideal for the pelvic floor 14 cavity in terms of pore size. 15 Q. And is that based on your 16 review of literature? 17 A. Yes, sir. 18 Q. Okay. Do you have a background 19 or degree in relation to the pore size of 20 pelvic mesh? 21 A. Do I have a background or 22 degree in relationship to the pore size of 23 the mesh? No, I do not. 24 Q. Have you ever consulted with a</p>

<p style="text-align: right;">Page 38</p> <p>1 mesh manufacturer regarding the pore size of 2 pelvic mesh? 3 A. I have not. 4 Q. Have you ever done any 5 research, outside of your literature review, 6 concerning the pore size of pelvic mesh? 7 A. I have not. 8 Q. Have you ever published any 9 peer-reviewed publications concerning the 10 pore size of pelvic mesh? 11 A. I have not. 12 Q. Flip over to page 25 of your 13 general report, which is Exhibit 6. On 14 page 25, you've got some information about 15 pore size and weave. Is that based solely on 16 your review of the medical literature? 17 A. Yes, and then what I've seen in 18 my own patients. 19 Q. Okay. Have you done any 20 independent research regarding the pore size 21 of the TVT mesh? 22 A. No. 23 Q. And I'm talking about outside 24 the literature review.</p>	<p style="text-align: right;">Page 40</p> <p>1 weave of pelvic mesh? 2 A. No. 3 Q. Okay. And I've already asked 4 you about the weave in the previous one. 5 Do you consider yourself an 6 expert in the weight or density of pelvic 7 mesh? 8 A. In terms of knowing what's 9 ideal for the pelvic floor cavity, yes. 10 Q. Okay. Have you ever done any 11 research on what's ideal for the weight or 12 density of pelvic mesh in the pelvic floor 13 cavity? 14 A. I have not. 15 Q. Do you have a background or 16 degree in weight or density of pelvic floor 17 mesh? 18 A. I do not. 19 Q. Ever consulted with a mesh 20 manufacturer concerning the weight or density 21 of pelvic floor mesh? 22 A. I have not. 23 Q. Outside of your literature 24 review for your general opinion -- your</p>
<p style="text-align: right;">Page 39</p> <p>1 A. No. No, sir. 2 Q. Now -- or the weave of the TVT 3 mesh? 4 A. No. 5 Q. Okay. Do you consider yourself 6 an expert in the weave of the TVT -- of 7 pelvic mesh? 8 A. I consider myself an expert in 9 terms of the type of materials that I need to 10 use to implant in pelvic floor surgery. 11 Q. Do you have a background or 12 degree in the weave of pelvic mesh? 13 A. I do not have a degree in 14 pelvic weave mesh construction. 15 Q. Okay. Have you ever consulted 16 with a mesh manufacturer concerning the weave 17 of pelvic mesh? 18 A. I have not. 19 Q. Outside of your literature 20 review, have you done any research concerning 21 the weave of pelvic mesh? 22 A. I have not. 23 Q. Have you ever published any 24 peer-reviewed publications concerning the</p>	<p style="text-align: right;">Page 41</p> <p>1 general report, have you done any research 2 concerning the weight and density of pelvic 3 mesh? 4 A. No. 5 Q. Have you ever published a 6 peer-reviewed publication concerning the 7 weight or density of pelvic floor mesh? 8 A. No. 9 Q. On page 25 to 26 of your 10 report, which is marked as Exhibit 6, you've 11 got information regarding mesh weight or 12 density. Is all that information based 13 solely on your review of medical -- review of 14 medical literature? 15 A. And my experience with 16 patients. 17 Q. All right. Have you done any 18 testing on weight or density of pelvic mesh? 19 A. I have not. 20 Q. Do you consider yourself an 21 expert in the absorption of pelvic mesh? 22 A. In terms of how it's applied to 23 patients, but not in terms of doing 24 scientific research.</p>

<p style="text-align: right;">Page 42</p> <p>1 Q. So you don't have a background 2 or degree in relation to the absorption of 3 pelvic mesh? 4 A. No, sir. 5 Q. You've never -- have you ever 6 consulted with a mesh manufacturer concerning 7 absorption of pelvic mesh? 8 A. No. 9 Q. I'm getting tongue-tied this 10 morning. Have you ever done -- outside of 11 your medical literature and your own 12 practice, have you ever done any research 13 into the absorption of pelvic mesh? 14 A. No. 15 Q. Have you ever published any 16 peer-reviewed articles regarding the 17 absorption of pelvic mesh? 18 A. No. 19 Q. Okay. Page 26 and 27, you've 20 got information regarding mesh absorption. 21 Is that based on your review of literature 22 and your own practice? 23 A. Yes. 24 Q. It's not based on any</p>	<p style="text-align: right;">Page 44</p> <p>1 the biocompatibility of pelvic mesh? 2 A. No. 3 Q. You've never implanted it in 4 any type of tissue, whether animal, human, 5 anything, and then pulled it out to see what 6 happens to it? 7 A. I have not. 8 Q. Have you ever published any 9 articles in peer-reviewed publications 10 concerning the biocompatibility of pelvic 11 mesh? 12 A. No. 13 Q. Are you an expert in 14 biomaterials? 15 A. I am an expert in terms of 16 implanting these materials in pelvic floor 17 surgery. 18 Q. Okay. But are you an expert in 19 how these materials react once they're 20 implanted in the body, the chemical 21 properties of the mesh, et cetera? 22 A. Clinically. 23 Q. Clinically. Outside of your 24 own clinical practice, have you done any</p>
<p style="text-align: right;">Page 43</p> <p>1 independent research you've done? 2 A. No. 3 Q. Do you consider yourself an 4 expert in the biocompatibility of pelvic 5 mesh? 6 A. In using -- in the application 7 to the clinical aspect of it. 8 Q. Okay. You don't have a -- do 9 you have a degree or -- strike that. 10 Outside of the clinical 11 practice, do you have any expertise in 12 biocompatibility of pelvic mesh? 13 A. No. 14 Q. Do you have a background or 15 degree related to the biocompatibility of 16 pelvic mesh? 17 A. No. 18 Q. Have you ever consulted a mesh 19 manufacturer concerning the biocompatibility 20 of pelvic mesh? 21 A. I have not. 22 Q. Have you ever done any 23 research, outside of the literature review 24 and your own clinical practice, concerning</p>	<p style="text-align: right;">Page 45</p> <p>1 testing concerning biomaterial issues related 2 to pelvic mesh? 3 A. No. 4 Q. Have you ever consulted with a 5 mesh manufacturer concerning biomaterial 6 issues related to pelvic mesh? 7 A. No. 8 Q. Outside of your literature 9 review and your own clinical practice, have 10 you ever done any research concerning the 11 biomaterial characteristics of pelvic mesh? 12 A. No. 13 Q. Have you ever published an 14 article in any peer-reviewed publications 15 concerning biomaterial issues involving 16 pelvic mesh? 17 A. No. 18 Q. Flip over to page 28. We're 19 going to try to go through some issues in the 20 actual report. And you've got some 21 information on host cell removal. And it 22 looks like this is on allografts. Do you see 23 where I'm talking about on page 28? 24 A. I do.</p>

<p style="text-align: right;">Page 46</p> <p>1 Q. Have you ever been involved 2 with preparing fascia lata or cadaver 3 material for use as an implant in the body? 4 A. No. 5 Q. In your report, you say it -- 6 "this is tricky." Where does that 7 information -- where does that come from? 8 A. Based upon the literature. 9 Q. Is that your characterization 10 of -- of it based on your review of the 11 literature? 12 A. Based upon the review. 13 Q. I'm going to -- you cite in 14 there an article by Fitzgerald. 15 A. Yes. 16 Q. "The antigenicity" -- I'm 17 probably butchering it with my Alabama 18 accent. 19 A. You did a good job. 20 Q. -- "of fascia lata allografts." 21 And we're going to mark this as Exhibit 8. 22 (Deposition Exhibit 8 marked.) 23 BY MR. LAMPKIN: 24 Q. I'm going to show you a copy of</p>	<p style="text-align: right;">Page 48</p> <p>1 BY MR. LAMPKIN: 2 Q. And in that, you reference the 3 Surgeon's Resource Monograph. 4 A. Correct. 5 Q. Okay. And then you go through, 6 and it looks -- I'm going to show you what 7 I'm going to mark as Exhibit 9 to your 8 deposition. I'll try to put this where it 9 doesn't cover something up. 10 (Deposition Exhibit 9 marked.) 11 BY MR. LAMPKIN: 12 Q. Is that the material you're 13 citing there on page 32 and 33? 14 A. Surgeon's monograph, yes. 15 Q. It appears that what you 16 have -- this says -- the outline. Did you 17 just kind of go through the table of contents 18 and provide the outline? 19 A. Partially, and then, of course, 20 I read it, as well. 21 Q. Okay. 22 A. And I'm familiar with it since 23 I've performed several of these surgeries. 24 Q. All right. Were you trained by</p>
<p style="text-align: right;">Page 47</p> <p>1 the Fitzgerald article. Is that the article 2 that you cite? 3 A. Yes. 4 Q. I read through the article, and 5 I didn't see the word "tricky" in it. That's 6 what's throwing me. Is "tricky" your 7 editorial comment based on -- 8 MR. OLIVEIRA: Objection, form. 9 BY MR. LAMPKIN: 10 Q. -- your review of that article? 11 A. Based upon what I have reviewed 12 in general regarding this particular topic. 13 Q. Okay. Have you done any 14 research, outside of your medical literature 15 review, regarding host cell removal from 16 cadaveric or fascia lata material? 17 A. Outside of the research, no. 18 Q. Let's flip over to page 32 to 19 33 of your deposition. 20 MR. OLIVEIRA: You mean of her 21 report? 22 MR. LAMPKIN: Of her report. 23 I'm sorry. Thank you. 24</p>	<p style="text-align: right;">Page 49</p> <p>1 Ethicon to perform these surgeries? 2 A. On -- for TVT, no. 3 Q. So did you place -- the actual 4 Gynecare TVT device, did you implant those 5 without any specific training from Ethicon? 6 A. I had already been doing 7 midurethral slings, and so there was a 8 proctor who had been trained by Ethicon and 9 then, of course, we also had the Ethicon rep 10 as well, and -- you know, so I already had 11 the experience of how to do the procedure but 12 not specifically the Ethicon product or their 13 specific training course. I had gone to 14 another training course. 15 Q. Had -- you had been trained on 16 the AMS product before? 17 A. Correct. 18 Q. Okay. And then you started 19 doing the Gynecare TVT -- 20 A. Correct. 21 Q. -- is that right? Did you -- 22 you said you had a proctor and an Ethicon 23 rep. Did you actually go and observe a 24 Gynecare TVT implant before you ever started</p>

<p style="text-align: right;">Page 74</p> <p>1 as the incision is made in the vaginal --</p> <p>2 anterior vaginal wall on a retropubic TVT, it</p> <p>3 comes around here and it exits, typically.</p> <p>4 So if we're going -- it's hard for me to show</p> <p>5 it with this here. But there is -- this</p> <p>6 area, there's minimal traversing through</p> <p>7 those muscles here in placing the TVT.</p> <p>8 BY MR. LAMPKIN:</p> <p>9 Q. But my question is, is that a</p> <p>10 risk of piercing --</p> <p>11 A. It's very unlikely.</p> <p>12 Q. Very unlikely. Are you</p> <p>13 familiar with the Rahn article regarding the</p> <p>14 anatomical path of tension-free vaginal tape?</p> <p>15 A. Let me see that.</p> <p>16 (Deposition Exhibit 15 marked.)</p> <p>17 BY MR. LAMPKIN:</p> <p>18 Q. By Dr. David Rahn and others,</p> <p>19 including doctor -- do you know Dr. Joseph</p> <p>20 Schaffer up at UT Southwestern?</p> <p>21 A. I've only learned of him</p> <p>22 through this -- through these cases.</p> <p>23 Q. Okay.</p> <p>24 A. But I don't know him, to answer</p>	<p style="text-align: right;">Page 76</p> <p>1 Q. My question is, if in the</p> <p>2 process of implanting the Gynecare TVT</p> <p>3 device, the trocar or the needle passes</p> <p>4 through one of the levator ani muscles there</p> <p>5 in the area of the vagina, could that result</p> <p>6 in pelvic pain or -- pelvic pain?</p> <p>7 A. It's possible, but there's a</p> <p>8 very low risk of that occurring, particularly</p> <p>9 because there's very -- a small passage</p> <p>10 through that.</p> <p>11 Q. Okay. But in that cadaveric</p> <p>12 study, it occurred 25 percent of the time.</p> <p>13 Would you agree with that?</p> <p>14 A. That's what this particular</p> <p>15 study indicates here.</p> <p>16 Q. All right. And if it passed</p> <p>17 through that, if it -- if the mesh passed</p> <p>18 through the levator ani muscle during</p> <p>19 implant, could it cause chronic pelvic pain?</p> <p>20 A. I don't know that it can cause</p> <p>21 chronic pelvic pain. I don't have -- I don't</p> <p>22 know of any literature indicating that.</p> <p>23 Q. Could you rule that out as a</p> <p>24 cause of chronic pelvic pain?</p>
<p style="text-align: right;">Page 75</p> <p>1 your question.</p> <p>2 Q. Does this appear to be a</p> <p>3 cadaver study regarding the implant of the</p> <p>4 Gynecare TVT device?</p> <p>5 (Witness Reviews Document.)</p> <p>6 A. Yeah, cadaveric. I mean, yes.</p> <p>7 BY MR. LAMPKIN:</p> <p>8 Q. Okay. Look under the results</p> <p>9 on the first page. We'll just go through the</p> <p>10 summary. The second sentence -- the third</p> <p>11 sentence says, "The sling passed lateral to</p> <p>12 the arcus tendineus and perforated the</p> <p>13 pubococcygeus muscle in 6 (25%) of the</p> <p>14 cadavers."</p> <p>15 A. I see that.</p> <p>16 Q. So if the TVT went through that</p> <p>17 muscle, could there be pain in that muscle</p> <p>18 due to the passage of the TVT through it?</p> <p>19 A. There -- I mean, this only</p> <p>20 indicates that it goes through that muscle.</p> <p>21 It doesn't indicate the -- well, first of</p> <p>22 all, earlier you mentioned inflammation or</p> <p>23 pain or dyspareunia related to that. So</p> <p>24 repeat your question.</p>	<p style="text-align: right;">Page 77</p> <p>1 A. The piercing through the</p> <p>2 levator ani muscle?</p> <p>3 Q. Uh-huh.</p> <p>4 A. You would have to look at all</p> <p>5 the potential causes.</p> <p>6 Q. Okay. If -- my question is,</p> <p>7 would you be able to rule that out as a</p> <p>8 potential cause?</p> <p>9 A. Without having perhaps an MRI</p> <p>10 to show inflammation or some other studies,</p> <p>11 you can't 100 percent rule that out.</p> <p>12 Q. We're done with that one. I</p> <p>13 want to talk to you on page 50, and it's</p> <p>14 actually page -- I think 49 and 50, where we</p> <p>15 talked about the sheaths earlier. And then</p> <p>16 you talk about the mesh, whether it's laser</p> <p>17 cut or mechanical cut.</p> <p>18 And then you've got, "Some</p> <p>19 expert witnesses retained by plaintiffs may</p> <p>20 argue mechanical cut mesh leads to fraying</p> <p>21 and loss of particles leading to pain.</p> <p>22 However, this has not been shown to occur."</p> <p>23 Is that right?</p> <p>24 A. In the research, I haven't seen</p>

<p style="text-align: right;">Page 78</p> <p>1 it, nor in my patients.</p> <p>2 Q. "I have not seen any literature</p> <p>3 that discusses particle loss leading to pain,</p> <p>4 nor have I seen it in my practice."</p> <p>5 A. Correct.</p> <p>6 Q. Okay. If -- have you gone back</p> <p>7 in and looked, after you've implanted mesh,</p> <p>8 to see if there's any particle loss?</p> <p>9 A. Have I, personally? I have</p> <p>10 not.</p> <p>11 Q. Okay. Before you got involved</p> <p>12 in this litigation, were you aware of this</p> <p>13 issue of particle loss regarding the TVT --</p> <p>14 mechanically cut TVT mesh?</p> <p>15 A. In terms of just the occurrence</p> <p>16 of it?</p> <p>17 Q. Uh-huh. That it could happen.</p> <p>18 A. Well, I mean, whenever you take</p> <p>19 out a mesh material, there is -- sometimes</p> <p>20 you see little flakes of things.</p> <p>21 Q. Okay. How many meshes have you</p> <p>22 taken out?</p> <p>23 A. Let's see. I would say</p> <p>24 approximately -- this is a guess -- 20, 25.</p>	<p style="text-align: right;">Page 80</p> <p>1 be on this one, I think. It might actually</p> <p>2 be on the flash drive, because this has</p> <p>3 these. I don't see that one in there. It's</p> <p>4 probably on the flash drive.</p> <p>5 Q. But that -- would that be the</p> <p>6 only copy -- if that's a company document,</p> <p>7 would that be the only one you reviewed?</p> <p>8 A. That I can recall. That's why</p> <p>9 when you asked me at first, I didn't recall.</p> <p>10 And so I need to correct that answer.</p> <p>11 Q. Okay.</p> <p>12 A. I believe so, but I can't tell</p> <p>13 you with 100 percent confirmation.</p> <p>14 Q. All right.</p> <p>15 A. I don't think it's in here.</p> <p>16 It's probably on my flash drive.</p> <p>17 Q. Okay. That's fine. I'll take</p> <p>18 a look at that later.</p> <p>19 (Deposition Exhibit 16 marked.)</p> <p>20 BY MR. LAMPKIN:</p> <p>21 Q. I'm going to show you what I'm</p> <p>22 going to mark as Exhibit 16. And I'll</p> <p>23 represent to you this is an Ethicon company</p> <p>24 document from 1998. And it's a surgeon</p>
<p style="text-align: right;">Page 79</p> <p>1 Q. And you did not review any</p> <p>2 Ethicon company documents in order to prepare</p> <p>3 your general report; is that right?</p> <p>4 A. Well, I know you asked me that</p> <p>5 earlier, and then I started to reflect</p> <p>6 upon -- I know there was one, except I can't</p> <p>7 remember exactly what that was. It may have</p> <p>8 been what you're going to go and allude to.</p> <p>9 Yeah, here it is. Is that the memo?</p> <p>10 Q. I see some flow memo, CPC --</p> <p>11 A. Flatow.</p> <p>12 Q. I'm sorry, Flatow?</p> <p>13 A. I don't know how to pronounce</p> <p>14 it.</p> <p>15 Q. Is that a -- is that a company</p> <p>16 document, or is that -- or is that some sort</p> <p>17 of research study?</p> <p>18 A. I believe -- let me pull it</p> <p>19 up --</p> <p>20 Q. Okay.</p> <p>21 A. -- since we have the materials</p> <p>22 here, so I can tell you for sure. So that</p> <p>23 was one, Flatow -- I'm going to have to</p> <p>24 pull -- let's see. Actually, no. It should</p>	<p style="text-align: right;">Page 81</p> <p>1 feedback on mesh concept. Did you review</p> <p>2 this document?</p> <p>3 A. I did not.</p> <p>4 Q. Okay. Flip over to the second</p> <p>5 page of the document. And this is an</p> <p>6 interview with a Dr. Fischer from Wiesbaden,</p> <p>7 Germany. Do you see down toward the bottom</p> <p>8 of the page?</p> <p>9 A. Uh-huh. Yes, I do.</p> <p>10 Q. And the second paragraph under</p> <p>11 Dr. Fischer is -- does it say, "Gynemesh is</p> <p>12 perceived as too bulky, and rigid. And when</p> <p>13 cutting the mesh, small particles are</p> <p>14 released that migrate through the vaginal</p> <p>15 wall causing pain"?</p> <p>16 A. I see that here.</p> <p>17 Q. Okay. Flip over to -- you see</p> <p>18 the little numbers at the bottom, the</p> <p>19 ETH.MESH, the Bates label numbers? You may</p> <p>20 not be familiar with the Bates label numbers.</p> <p>21 A. This down here?</p> <p>22 Q. Yes. Flip over to page 168,</p> <p>23 and we're going to go to 169. But 168 is a</p> <p>24 Dr. Hilton from Newcastle upon Tyne in the</p>

<p style="text-align: right;">Page 82</p> <p>1 UK.</p> <p>2 A. Uh-huh.</p> <p>3 Q. And if you flip over to</p> <p>4 page 169, you see the last sentence of the</p> <p>5 first paragraph -- the continuation of the</p> <p>6 paragraph at the top?</p> <p>7 A. Yes.</p> <p>8 Q. "The small particles migrate</p> <p>9 and cause pain during intercourse."</p> <p>10 A. Yes.</p> <p>11 Q. Were you aware that Ethicon was</p> <p>12 on notice as of 1998 that particles of this</p> <p>13 mesh could break off and cause pain in the</p> <p>14 pelvis?</p> <p>15 MR. OLIVEIRA: Objection, form.</p> <p>16 A. I'm not aware of that.</p> <p>17 BY MR. LAMPKIN:</p> <p>18 Q. Did you consider that in your</p> <p>19 portion of the -- on page 50 of your report,</p> <p>20 where you talk about it's not been shown to</p> <p>21 occur that the mesh frays and particles break</p> <p>22 off?</p> <p>23 A. Well, this -- this isn't a</p> <p>24 research study here.</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. And on the first page of this</p> <p>2 document, in the first paragraph, it says,</p> <p>3 "This note to file will address complaints of</p> <p>4 TVT Tension-free Support for Incontinence</p> <p>5 mesh fraying during placement."</p> <p>6 Then, "Since the introduction</p> <p>7 of the device in 2000, there have been a</p> <p>8 total of 58 complaints of fraying. Fraying</p> <p>9 is inherent in the design and construction of</p> <p>10 the product."</p> <p>11 Were you aware that fraying was</p> <p>12 inherent in the design and construction of</p> <p>13 the product?</p> <p>14 A. In what reference? Just the --</p> <p>15 just fraying in general --</p> <p>16 Q. Yes.</p> <p>17 A. -- versus how it applies</p> <p>18 clinically or -- in general --</p> <p>19 Q. In general. Let's take in</p> <p>20 general.</p> <p>21 A. Okay. No.</p> <p>22 Q. Okay. Then it says, "The</p> <p>23 application of tension exacerbates this</p> <p>24 issue. When the mesh frays, several events</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. Okay. But this is information</p> <p>2 that Ethicon, who hired you to testify in</p> <p>3 this case, had and was aware of. Did Ethicon</p> <p>4 make -- were you aware that Ethicon knew, as</p> <p>5 far back as 1998, that these -- this mesh</p> <p>6 could fray and particles would break off and</p> <p>7 those particles could cause dyspareunia and</p> <p>8 cause pelvic pain?</p> <p>9 MR. OLIVEIRA: Objection, form.</p> <p>10 A. Well, at this point, it's</p> <p>11 been -- '99 -- 16, 17 years, and that hasn't</p> <p>12 been shown to be the case.</p> <p>13 BY MR. LAMPKIN:</p> <p>14 Q. Okay. I'm going to show you</p> <p>15 what we're going to mark as Exhibit 17 to</p> <p>16 your deposition.</p> <p>17 (Deposition Exhibit 17 marked.)</p> <p>18 BY MR. LAMPKIN:</p> <p>19 Q. And I'll represent to you this</p> <p>20 is an Ethicon document from November 18th,</p> <p>21 2003, from a Marty Weisberg, senior medical</p> <p>22 director, Gynecare, which is an Ethicon</p> <p>23 division.</p> <p>24 A. Okay.</p>	<p style="text-align: right;">Page 85</p> <p>1 occur: The mesh elongates in places; the</p> <p>2 mesh narrows in places; and small particles</p> <p>3 of Prolene might break off."</p> <p>4 A. Okay.</p> <p>5 Q. This is Gynecare's document</p> <p>6 saying that this happens; is that right?</p> <p>7 A. That's what that says here.</p> <p>8 Q. Okay.</p> <p>9 A. But that doesn't -- I don't see</p> <p>10 how that's applicable clinically in terms of</p> <p>11 that being -- showing a cause and effect.</p> <p>12 Q. Was that 17?</p> <p>13 A. Yes, it is.</p> <p>14 Q. Were you aware that the very</p> <p>15 act of implanting the Gynecare TVT device can</p> <p>16 cause the fraying that's talked about in that</p> <p>17 article regarding the inherent design of it?</p> <p>18 A. I'm aware that overtensioning</p> <p>19 can cause some changes in the TVT mesh.</p> <p>20 Q. Okay. My question is not -- I</p> <p>21 understand overtensioning, but are you aware</p> <p>22 that the very fact of removing the sheaths</p> <p>23 can cause the problems with fraying and mesh</p> <p>24 particles breaking off?</p>

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1 MR. OLIVEIRA: Objection, form.
2 A. Specifically the fraying and
3 particle loss?
4 BY MR. LAMPKIN:
5 Q. Uh-huh.
6 A. I'm aware of that, but not as
7 to it leading to any clinical adverse events.
8 (Deposition Exhibit 18 marked.)
9 BY MR. LAMPKIN:
10 Q. I'll show you what I'm marking
11 as Exhibit 18. Have you ever seen that
12 document before?
13 A. So far it doesn't look
14 familiar.
15 Q. Okay. This is a April 19th,
16 2004, e-mail from Gene Kammerer to others at
17 Ethicon. And if you look down at 2a, it
18 says, "The link between the elongation
19 percent, not force, and the integrity of the
20 mesh is this: During the operative
21 procedure, as the surgeon removes the
22 protective sheath from the mesh, the mesh
23 stretches or elongates. It is my experience,
24 after viewing many surgical procedures, and

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1 performing numerous procedures on cadavers
2 myself, that the mesh stretches approximately
3 50 percent at the maximum. There is also
4 additional stretching which occurs if the
5 surgeon elects to do an adjustment on the
6 position of the mesh under the urethra. It
7 is these two occurrences which produce the
8 majority of the particle loss and loss of
9 integrity of the construction of the mesh.
10 The particle loss is measured objectively by
11 weight difference before and after
12 stretching. The mesh integrity is measured
13 subjectively by observation of the number of
14 knit points that have been lost."
15 Is that what that document
16 says?
17 A. That's what that -- that's what
18 that states.
19 Q. Okay. Were you aware that the
20 very act of removing the protective sheaths
21 from the TVT mesh could cause the loss of
22 integrity of the mesh through elongation and
23 particle loss?
24 A. No, but that -- I don't see how

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1 that -- this is one document, and how -- how
2 this applies clinically and where you see it
3 in research, I guess, would be my question.
4 Q. Okay. I'm going to show you
5 what I'm going to mark as Exhibit 19.
6 (Deposition Exhibit 19 marked.)
7 BY MR. LAMPKIN:
8 Q. This is another e-mail from
9 Gene Kammerer dated August 28, 2006. And it
10 says, "Attached is the PPT file with some
11 photos of the LCM" -- which I'll represent to
12 you is laser cut mesh -- "vs MCM" --
13 mechanically cut mesh -- "after elongation @
14 50%." Is that right?
15 A. That's what that says, correct.
16 Q. Okay. If you will flip over --
17 and the pages are not numbered, I'm sorry.
18 If you flip over to where it says description
19 of the results.
20 A. Okay.
21 Q. Says, "The MCM" -- the third
22 bullet point. "The MCM samples show
23 degradation of the structure of the mesh in
24 certain areas where, because of particle

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1 loss, the knit is opened and a portion of the
2 construction has been lost. The area may
3 also be stretched and narrowed resulting in
4 roping due to this occurrence."
5 A. I read that, correct.
6 Q. Were you aware of that?
7 A. No. But this is one -- how
8 many times was this done? I guess -- I guess
9 I'd like to read a little more to be able to
10 make my opinions on this.
11 Q. Look over to the next page. It
12 says, "Side by Side."
13 A. Uh-huh. I'm there.
14 Q. Okay. You see it's got MCM and
15 it's got two pieces of mesh?
16 A. Yes.
17 Q. And then you've got LCM?
18 A. Yes.
19 Q. And then you -- it's got
20 degradation and particles on the MCM side?
21 A. Yes.
22 Q. You see the little blue flakes
23 that have come off of that?
24 A. I see that.

<p style="text-align: right;">Page 90</p> <p>1 Q. Okay. Are you aware of any 2 studies that Johnson & Johnson -- or Ethicon 3 undertook to find out what was going on when 4 this mesh was stretched and particles broke 5 off, what was happening in -- to women that 6 had the mesh implanted?</p> <p>7 MR. OLIVEIRA: Objection, form.</p> <p>8 A. Not specifically to that.</p> <p>9 However, there's been millions of women who 10 have had the TVT placed. And so with having 11 the results and the outcomes of those 12 patients, then we're able to determine -- or 13 to identify how the mesh is reacting and how 14 they're responding to it, both in 15 complications and in efficacy.</p> <p>16 BY MR. LAMPKIN:</p> <p>17 Q. Go back to the Petri article.</p> <p>18 MR. OLIVEIRA: Which exhibit is 19 that?</p> <p>20 MR. LAMPKIN: Petri is 21 Exhibit 11.</p> <p>22 A. I have it here.</p> <p>23 MR. OLIVEIRA: You have it 24 there?</p>	<p style="text-align: right;">Page 92</p> <p>1 A. Again, I haven't fully read 2 this to tell you besides what -- to answer 3 your question, except for the fact that 4 that's what that reads here.</p> <p>5 Q. Okay.</p> <p>6 MR. LAMPKIN: All right. Why 7 don't we take a short break. We've 8 been going -- and I hope to be done in 9 just a few minutes.</p> <p>10 MR. OLIVEIRA: Okay.</p> <p>11 THE VIDEOGRAPHER: Going off 12 the record -- going off the record, 13 the time is 9:51.</p> <p>14 (Recess Taken From 9:51 a.m. To 15 10:06 a.m.)</p> <p>16 THE VIDEOGRAPHER: Back on the 17 record. The time is 10:06.</p> <p>18 BY MR. LAMPKIN:</p> <p>19 Q. Dr. Irwin, before we took the 20 break, we were talking about pain and we were 21 talking about the fraying-of-the-mesh issue. 22 And in this -- in your report, you say you 23 have not seen any literature to discuss this 24 particle loss that leads -- leading to pain.</p>
<p style="text-align: right;">Page 91</p> <p>1 THE WITNESS: Yeah.</p> <p>2 BY MR. LAMPKIN:</p> <p>3 Q. Does the Petri article on 4 the -- say, "Compared to the retropubic tape 5 group, the transobturator group had more 6 number of complications related to persistent 7 pain"?</p> <p>8 I'm looking at the bottom of 9 the first column, on the first page, and then 10 the top of the second column.</p> <p>11 A. That's what this reads, 12 correct.</p> <p>13 Q. And it says, "(10% tension-free 14 vaginal tapes vs. 32% transobturator tapes)"? 15 (Witness Reviews Document.)</p> <p>16 A. Okay. So your question is --</p> <p>17 BY MR. LAMPKIN:</p> <p>18 Q. My question is, is that what 19 this study finds, is 10 percent TVT pain -- 20 persistent pain after implant of a TVT 21 device?</p> <p>22 A. That's what that indicates 23 here.</p> <p>24 Q. And --</p>	<p style="text-align: right;">Page 93</p> <p>1 There is medical literature 2 that discusses persistent and chronic pain 3 related to TVT devices. Would you agree with 4 that?</p> <p>5 A. In terms of the chronic pain in 6 general --</p> <p>7 Q. Chronic pain --</p> <p>8 A. -- is what you're asking me?</p> <p>9 Q. Right.</p> <p>10 A. Yes.</p> <p>11 Q. We don't know whether it's in 12 particular to the particle loss, but there 13 are -- there is literature out there, as we 14 showed with Petri, that discusses persistent 15 or chronic pelvic pain --</p> <p>16 A. Yes.</p> <p>17 Q. -- related to the TVT?</p> <p>18 A. There is.</p> <p>19 Q. On page 54 of your report you 20 use the term "fibroblast reaction," if I'm 21 pronouncing it correctly. What do you mean 22 by that?</p> <p>23 (Witness Reviews Document.)</p> <p>24 A. So in terms of knowing, you</p>

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CERTIFICATE

I, MICHEAL A. JOHNSON, Registered
Diplomate Reporter, Certified Realtime
Reporter, Certified Court Reporter and Notary
Public, do hereby certify that prior to the
commencement of the examination, TERESA
IRWIN, M.D. was duly sworn by me to testify
to the truth, the whole truth and nothing but
the truth.

I DO FURTHER CERTIFY that the
foregoing is a verbatim transcript of the
testimony as taken stenographically by and
before me at the time, place and on the date
hereinbefore set forth, to the best of my
ability.

I DO FURTHER CERTIFY that pursuant
to FRCP Rule 30, signature of the witness was
not requested by the witness or other party
before the conclusion of the deposition.

I DO FURTHER CERTIFY that I am
neither a relative nor employee nor attorney
nor counsel of any of the parties to this
action, and that I am neither a relative nor
employee of such attorney or counsel, and
that I am not financially interested in the
action.



MICHEAL A. JOHNSON, RDR, CRR
NCRA Registered Diplomate Reporter
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Certified Court Reporter

Notary Public in and for the
State of Texas
My Commission Expires: 8/8/2016

Dated: March 29, 2016